

action by the respondent; waive or modify these procedures in a specific case, usually with notice to the parties; reconsider a decision of the reviewing official where a party promptly alleges a clear error of fact or law; and to take any other action necessary to resolve disputes in accordance with the objectives of the procedures in this subpart.

§ 8.32 Administrative record.

The administrative record of review consists of the review file; other submissions by the parties; transcripts or other records of any meetings, conference calls, or oral presentation; evidence submitted at the oral presentation; and orders and other documents issued by the reviewing and presiding officials.

§ 8.33 Written decision.

(a) *Issuance of decision.* The reviewing official shall issue a written decision upholding or denying the suspension, proposed revocation, or adverse action. The decision will set forth the reasons for the decision and describe the basis for that decision in the record. Furthermore, the reviewing official may remand the matter to the respondent for such further action as the reviewing official deems appropriate.

(b) *Date of decision.* The reviewing official will attempt to issue the decision within 15 days of the date of the oral presentation, the date on which the transcript is received, or the date of the last submission by either party, whichever is later. If there is no oral presentation, the decision will normally be issued within 15 days of the date of receipt of the last reply brief. Once issued, the reviewing official will immediately communicate the decision to each party.

(c) *Public notice and communications to the Drug Enforcement Administration (DEA).* (1) If the suspension and proposed revocation of OTP certification are upheld, the revocation of certification will become effective immediately and the public will be notified by publication of a notice in the FEDERAL REGISTER. SAMHSA will notify DEA within 5 days that the OTP's registration should be revoked.

(2) If the suspension and proposed revocation of OTP certification are denied, the revocation will not take effect and the suspension will be lifted immediately. Public notice will be given by publication in the FEDERAL REGISTER. SAMHSA will notify DEA within 5 days that the OTP's registration should be restored, if applicable.

§ 8.34 Court review of final administrative action; exhaustion of administrative remedies.

Before any legal action is filed in court challenging the suspension, proposed revocation, or adverse action, respondent shall exhaust administrative remedies provided under this subpart, unless otherwise provided by Federal law. The reviewing official's decision, under § 8.28(e) or § 8.33(a), constitutes final agency action as of the date of the decision.

PART 9—STANDARDS OF CARE FOR CHIMPANZEES HELD IN THE FEDERALLY SUPPORTED SANCTUARY SYSTEM

Sec.

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- 9.12 Compliance with the Standards of Care, USDA and PHS policies and regulations.
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AUTHORITY: 42 U.S.C. 216, 287a–3a.

SOURCE: 73 FR 60423, Oct. 10, 2008, unless otherwise noted.

§ 9.1 Applicability and purpose.

(a) *General.* The standards of care set forth in this part apply to the chimpanzee sanctuaries that are contracted (or subcontracted) to the Federal Government to operate the federally supported chimpanzee sanctuary system

authorized by section 481C of the Public Health Service (PHS) Act, as amended (42 U.S.C. 287a–3a).

(b) *What is the purpose of the federally supported chimpanzee sanctuary system and the authority for establishing these standards of care regulation?* The Chimpanzee Health Improvement, Maintenance, and Protection Act (Pub. L. 106–551, referred to as the “CHIMP Act” or “Chimpanzee Retirement Act”) was enacted by Congress to provide for the establishment and operation of a sanctuary system to provide lifetime care for chimpanzees that have been used, or were bred or purchased for use, in research conducted or supported by the agencies of the Federal Government, and that are determined to be no longer needed for such research. The CHIMP Act also mandates that standards of care for chimpanzees in the sanctuary shall be developed to ensure the well-being of chimpanzees and the health and safety of the chimpanzees.

(c) *To what chimpanzee sanctuaries do the standards of care in this part apply?* The standards of care set forth in this part apply to only those sanctuaries that are contracted or subcontracted to the Federal Government to operate the federally supported chimpanzee sanctuary system.

§9.2 Definitions.

As used in this part:

Adequate veterinary care means a program directed by a veterinarian qualified through training and/or experience to provide professional medical care to the chimpanzees within the Sanctuary and with the appropriate authority to provide this care. The program also provides guidance to all caregivers on all matters relating to the health and well-being of the chimpanzees.

American Zoo and Aquarium Association (AZA) means the professional society composed of individuals with various backgrounds and interests that are devoted to advancing the knowledge and understanding of zoo animals and the management of zoos in the United States.

American Zoo and Aquarium Association (AZA) Accreditation Standards are those standards developed by the AZA that are used to review, evaluate, and accredit zoos or zoological gardens.

These standards cover a variety of areas including facilities, policies and procedures, training, staff qualifications, medical and animal care, husbandry and well-being procedures, and conservation, along with other specific areas.

Animal Care and Use Committee means the Institutional Animal Care and Use Committee established under section 13(b) of the Animal Welfare Act of 1985 and the Health Research Extension Act of 1985. For the purpose of these Standards of Care, it shall consist of at least five (5) members including the Chairperson, a Doctor of Veterinary Medicine (D.V.M. or V.M.D.) knowledgeable in nonhuman primate care and diseases and with delegated program responsibility, a member not affiliated with the Sanctuary, a scientist, and a member of the animal protection community. The requirement that a member of the ACUC must be from an animal protection organization is unique to this part and is not required under the Animal Welfare Regulations or the Public Health Service Policy on the Humane Care and Use of Laboratory Animals. This Committee must be established if research as defined by the Animal Welfare Act Regulations and the Public Health Service Policy (research, teaching, testing, exhibition) is to be conducted at the sanctuary.

Animal protection organization means a nonprofit organization whose primary mission is protection of animals through positive advocacy and action.

Animal Resource Manager (or Animal Resource Supervisor) means the individual employee responsible for managing the nonprofessional staff providing care for the chimpanzees at the sanctuary. This individual may perform other duties as assigned by the Sanctuary Contractor.

Animal Welfare Act/Regulations means the Act of August 24, 1966 (Pub. L. 89–544, commonly known as the Laboratory Animal Welfare Act), as amended by the Act of December 24, 1970 (Pub. L. 91–579, the Animal Welfare Act of 1970), the Act of April 22, 1976 (Pub. L. 94–279, the Animal Welfare Act of 1976), and the Act of December 23, 1985 (Pub. L. 99–198, the Food Security Act of 1985), and as may be subsequently amended, and the United States Department of

Agriculture (USDA) regulations implementing the Animal Welfare Act in title 9, chapter 1, subchapter A of the CFR.

Animal Welfare Assurance means the documentation from an institution assuring compliance with the PHS Policy on Humane Care and Use of Laboratory Animals. This policy is administered by the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health.

Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC) means the nonprofit organization that is recognized in the United States and abroad as being the body responsible for the accreditation of laboratory animal programs.

Behaviorist means a person hired by the sanctuary to administer or oversee the enrichment and behavioral program for the chimpanzees at the sanctuary. This individual must be qualified through training or experience.

Biosafety Officer means the individual responsible for establishing and monitoring workplace safety procedures designed to minimize or prevent injury or loss due to biohazards in accordance with policies established by the sanctuary administration.

Board of Directors (BOD) means the individuals selected by the Contractor to govern the nonprofit institution responsible for operating the federally supported chimpanzee Sanctuary system. The board members must meet the qualifications and criteria stated in the CHIMP Act.

Chair of the Board of Directors means the individual chosen by the BOD or other legally empowered entity to carry out such action, who is responsible for chairing meetings and acting on behalf of the board. This individual reports directly to the Board.

Chief Executive Officer (CEO) means the principal person responsible for overall accomplishment of the mission of the chimpanzee sanctuary.

CHIMP Act means the Chimpanzee Health Improvement, Maintenance, and Protection Act of December 20, 2000 (Pub. L. 106-551) commonly known as the "CHIMP Act" or "Chimpanzee Retirement Act," and any future amendments.

Chimpanzee means a member of *Pan troglodytes*. It excludes the pygmy chimpanzee (*Pan paniscus* or bonobo).

Chimpanzee caregivers (caregivers) mean all sanctuary technical and husbandry staff providing long-term care and services for the chimpanzees.

Contractor/Primary Contractor/Sanctuary Contractor means the nonprofit entity awarded a contract by the Federal Government to establish and operate the chimpanzee sanctuary system.

Euthanasia means the humane death of a chimpanzee accomplished by a method that produces rapid unconsciousness and subsequent death without evidence of pain or distress. The method must be consistent with the recommendations of the American Veterinary Medical Association Panel on Euthanasia.

Exhibition means exhibiting chimpanzees to the public for compensation. This definition excludes limited viewing for educational purposes that are not disruptive to the chimpanzees.

Facility director means the individual responsible for directing the overall activities at the Sanctuary site.

Facility Veterinarian means a person who has graduated from a veterinary school accredited by the American Veterinary Medical Association (AVMA) Council on Education, or who has a certificate issued by the AVMA's Education Commission for Foreign Veterinary Graduates; has training and/or experience in the care and management of nonhuman primates; and has direct or delegated authority for activities involving chimpanzees at the federally funded chimpanzee sanctuary.

Federal Acquisition Regulations (FAR) means the codified rules applicable to contracts, specifically those sections of the FAR (48 CFR chapter 1, part 52) that are applicable to contracts between the Federal Government and a contractor (in this case a private, nonprofit entity under contract to operate the chimpanzee sanctuary system).

Federal agency means an executive agency as such term is defined in section 105 of title 5, United States Code, and refers to the agency from which the research facility receives a Federal award for projects involving animals.

Federally owned chimpanzees mean chimpanzees that have been purchased

by, bred by, or donated to a federal agency for use in biomedical/behavioral research. Chimpanzees whose ownership was subsequently transferred from Federal ownership via written transfer agreements are no longer federally owned.

Guide means *The Guide for the Care and Use of Laboratory Animals*, published by the National Academy of Sciences, Institute for Laboratory Animal Research of the National Research Council, 1996, International Standard Book Number 0-309-05377-3.

Housing facility means any land, premises, shed, barn, building, trailer, or other structure or area housing intended to house chimpanzees.

Indoor housing facility refers to any structure or enclosure (for example, cages, pens, rooms) for maintaining animals in a controlled environment that provides for normal physiological and behavioral needs.

Interstate air transport live animals (IATA) regulations means those regulations and standards covering the air transportation of nonhuman primates developed and implemented by the International Air Transportation Association.

Invasive research (studies) utilizes those procedures that cause more than momentary pain, distress, fear, discomfort, injury, or other negative modalities to a chimpanzee. Any procedure that enters or exposes a body cavity is considered to be invasive. Sanctuary chimpanzees may not be used in invasive research. This definition excludes any invasive procedure that is a part of veterinary, medical, or surgical care that is performed by or under the direction of the Sanctuary Veterinarian using acceptable veterinary practices. Some examples of invasive studies are:

(1) Experimental exposure to a substance that may be detrimental to a chimpanzee's health (e.g., infectious disease, radiation). This does not include accidental exposures to infectious diseases transmitted from cage mates or from radiation or other exposures at the time of regularly scheduled or necessary veterinary examinations and treatments;

(2) Any invasion of a body cavity;

(3) Surgery and surgical implantation of devices that are not a part of a veterinary medical treatment or colony management purposes.

(4) Behavioral studies that cause distress or discomfort, such as induction of a fear response;

(5) Testing of any drug;

(6) Purposeful manipulation of social groups or the removal from their social group or addition of individuals in order to conduct behavioral research (for example, on aggression). Creation and refinement of social groups will be necessary when the animals arrive at the Sanctuary and this should take place only when necessary in regards to colony management and should not be driven by independently initiated research studies;

(7) Restraint unless it is in conjunction with the annual exam or clinical care; and

(8) Darting or anesthesia induction other than at annual exam or in the case of an emergency in which the chimpanzee's well-being is at stake.

National Primate Research Center (NPRC) means those centers supported by the National Center for Research Resources, National Institutes of Health, Department of Health and Human Services, as national resources for providing high-quality nonhuman primate research resources and facilities. As of June 2007, there were eight such centers.

National Research Council means the component of the National Academy of Sciences that advises the Federal Government on matters related to science, research, and research resources.

Nonfederally owned chimpanzees mean chimpanzees that have not been purchased by, bred by, or donated to the Federal Government for use in federally supported research projects. In accordance with the CHIMP Act, chimpanzees owned on the date of passage of the CHIMP Act by a National Primate Research Center may enter the sanctuary system without requiring the NPRC to pay a fee. Offspring born in the sanctuary is owned by the Sanctuary Contractor.

Noninvasive research (studies) means the use of procedures that depend upon close observation of chimpanzee behavior or on medical information collected

during the course of normal veterinary care. These procedures do not require removal of the chimpanzees from their social group or environment, or require a separate anesthetic or sedation event to collect data or record observations. Some examples of noninvasive studies are:

- (1) Visual observation;
- (2) Behavioral studies designed to improve the establishment and maintenance of social groups. These activities may cause stress as a result of novel interactions between chimpanzees and caregivers, but they are not considered invasive as long as they are intended to maximize the well-being of the chimpanzees;
- (3) Medical examinations as deemed necessary to oversee the health of the chimpanzees, in the least invasive manner possible. Collection of samples routinely obtained during a physical examination for processing during this time is also considered noninvasive since a separate event is not required;
- (4) Administration and evaluation of environmental enrichment used to promote the psychological well-being of the chimpanzees; and
- (5) Actions taken to provide essential medical treatment to an individual chimpanzee exhibiting symptoms of illness. This applies only to serious illness that cannot be treated while the chimpanzee remains within the colony.

Outdoor housing facility (area) means corrals, Primadomes (a prefabricated outdoor housing unit), fenced open areas, or similar structures or areas for maintaining chimpanzees with access to adequate protection from the extremes of environmental elements and harsh weather conditions.

Outdoor ranging area means an area that allows chimpanzees greater ranging space than corrals or other outdoor housing area and includes a variety of vegetation, shrubbery, grasses and trees, thereby providing for a fairly unrestricted natural setting for the chimpanzees to engage in species-appropriate activities. The area is secured by an outer perimeter barrier.

Project Officer means the individual designated by the Federal Government to represent the contracting officer and interests of the federal agency, within defined areas, in monitoring and over-

seeing the chimpanzee sanctuary system contract.

Sanctuary Chimpanzee Care Committee (SCCC) or similar designated committee means the group of individuals designated by the CEO of the sanctuary that reviews and monitors adherence to the policies, procedures, and regulations at the sanctuary.

Sanctuary Contractor means the non-profit, private entities selected by NCR/NH to develop and operate the chimpanzee sanctuary system. This contractor is also known as the "primary contractor" for the sanctuary system.

Sanctuary Director means the individual who provides day-to-day direction and oversight to the employees responsible for performing the daily tasks at the facility.

Sanctuary or federally supported chimpanzee sanctuary system means the sanctuary or sanctuary system established by the Federal Government through contracting with a private, nonprofit entity, for the purpose of carrying out the provisions of the CHIMP Act of 2000. The system includes a primary Contractor and may include additional subcontractors as required. This sanctuary system is supported primarily from funds allocated by NCR/NH/HHS with some matching funds from the nonprofit contractor.

Secretary means the Secretary of Health and Human Services or his/her designee.

Subcontractor means a private, non-profit entity selected by the primary contractor to provide additional sanctuary services.

Surplus chimpanzees means chimpanzees that are no longer needed in research and that were used, or were bred or purchased for use, in research conducted or supported by the Federal Government.

USDA licensed intermediate handler/carrier means any person, including a department, agency, or instrumentality of the United States or of any State or local government, who is engaged in any business in which it receives custody of animals in connection with their transportation in commerce and who is licensed by the USDA.

§9.3

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Zoonotic disease(s) means diseases that are transmissible from chimpanzees to humans.

§9.3 Sanctuary policies and responsibilities.

(a) *What are the policies and responsibilities governing the sanctuary system?* It will be the policies and responsibilities of the sanctuary system to:

(1) Appoint a Board of Directors (BOD) responsible for the overall governance and direction of the Sanctuary. The BOD shall designate the Chief Executive Officer (CEO), who is responsible for the management and oversight of the daily operations of the sanctuary and the performance of other delegated tasks. Subcontractors, if applicable, shall be governed by the policies that are developed by the Board of Directors of the primary contractor.

(2) Direct the BOD to:

(i) Ensure that chimpanzees accepted into the sanctuary are not discharged;

(ii) Develop guidelines for accepting chimpanzees not owned by the Federal Government into the sanctuary if the conditions are met as outlined in 42 U.S.C. 287;

(iii) Ensure that the Board of Directors of the primary contractor consists of no more than thirteen (13) individuals, and that the conditions governing the terms of the Board members are in compliance with the CHIMP Act;

(iv) Include individuals with the following expertise and experience as set forth in the CHIMP Act;

(A) At least one veterinarian who is qualified in veterinary care of nonhuman primates. These qualifications may be met through postdoctoral training, experience, or both;

(B) Individual(s) with expertise and experience in zoological science and with knowledge in behavioral primatology;

(C) Individual(s) with experience in the animal protection field;

(D) Individual(s) with experience and expertise in the field of business and management of nonprofit organizations;

(E) Individual(s) knowledgeable and experienced in accrediting programs of animal care;

(F) Individual(s) with experience and expertise in containing biohazards;

(v) Ensure that a member of the Board of Directors serves as the Chair of the Board of Directors, who may be elected or appointed by the Board from among the individuals identified in paragraphs (a) (1) (iv) (A) through (F) of this section;

(vi) Ensure that no member of the board shall have been fined for, or signed a consent decree for, any violation of the Animal Welfare Act;

(vii) Create a safe and species-appropriate physical and social environment for the lifetime care of chimpanzees;

(viii) Comply with all applicable provisions of the animal welfare regulations and other federal, state and local laws, regulations, and policies;

(ix) Achieve accreditations from appropriate accrediting bodies within a reasonable time frame mutually agreed upon by the Contractor and NCCR;

(x) Prohibit any invasive research on the resident chimpanzees, but permit noninvasive studies (Definitions for the terms *invasive* and *non-invasive* are set forth in §9.2 of this part.);

(xi) Prohibit exhibition of chimpanzees in the sanctuary (This policy does not prohibit educational activities that may involve limited viewing of chimpanzees in their environment and that are designed to promote an understanding of chimpanzee behavior, well-being, or importance to the ecological system that does not adversely affect the chimpanzees' routine.);

(xii) Staff the organization with people with appropriate experience; and

(xiii) Authorize the establishment of a Sanctuary Chimpanzee Care Committee (SCCC) that is appointed by and reports to the CEO or President of the company or corporation. The SCCC is responsible for overseeing the chimpanzee care program and operations to ensure the health and well-being of the chimpanzees and the occupational safety of the staff are being addressed. The Committee must consist of no fewer than five people who must include:

(A) A chair (person) knowledgeable of the needs of chimpanzees;

(B) A veterinarian with chimpanzee care experience;

(C) A behaviorist with experience in chimpanzee behavior;

(D) A member of the chimpanzee care staff; and

(E) Member or members from the community, including at least one with affiliation or employment with an animal protection organization as defined in §9.2 of this part.

(F) The SCCC will:

(1) Oversee and evaluate the chimpanzee care and socialization program;

(2) Review and approve proposed education programs. No program should be approved that might interfere with the chimpanzees' well-being or routine activities;

(3) Conduct a formal review of the program on a semiannual basis and submit reports to the Sanctuary Director. The reports must be available for review by the USDA and NIH representatives during site visits;

(4) Establish a mechanism for receipt and review of concerns involving the care of chimpanzees and resolving such concerns;

(5) Review all noninvasive study proposals. The SCCC membership may require additional qualified individuals to perform the functions of an Animal Care and Use Committee (ACUC) if and when the need arises. The contractor may establish a separate ACUC. The ACUC must be established in accordance with the applicable provisions of the Animal Welfare Act regulations, the Public Health Service Policy on Humane Care and Use of Laboratory Animals, and these standards of care;

(6) Review all euthanasia events. Euthanasia events performed for medical or humane reasons must be based upon sound professional veterinary judgment that conforms to current veterinary medical practices and must be in the best interest of the chimpanzee. Euthanasia performed for emergency reasons without advance review by the SCCC shall be reviewed by the SCCC as soon as possible after the event to ensure compliance with established policy;

(7) Establish procedures to prevent any reproduction in the colony through appropriate permanent birth control, preferably by vasectomy of all sexually mature male chimpanzees in the sanctuary; and

(8) Develop procedures for maintaining chimpanzees that are seropositive

for or harboring infectious agents or previously have been exposed to infectious agents (whether experimentally induced or naturally occurring) that will allow them to be accepted by the sanctuary and properly housed. The procedures must be submitted to NCCRR/NIH for approval.

(b) *Who is responsible for developing or revising sanctuary policies?* (1) The Sanctuary Contractor is responsible for developing, revising, and implementing policies affecting the sanctuary.

(2) The federal agency (NCCRR/NIH) designated by the Secretary must concur with any changes that substantially change existing policies. The Secretary, or designee, will determine if a policy change will have a substantial impact upon current policy after consultation with the Sanctuary Contractor.

§9.4 Physical facility policies and design.

(a) *What standards apply to the facility design and physical plant?* The chimpanzee sanctuary facility must be designed to provide sufficient space and variety of natural or artificial objects to accommodate natural activities of chimpanzees while restricting their movement and range to the defined area. Daily observation of chimpanzees within the enclosures is required and shall be accomplished with minimal disturbance to the chimpanzees. The facility design and physical plant should be in accordance with the recommendation of *The Guide for the Care and Use of Laboratory Animals (Guide)*, where applicable. The *Guide* is published by the National Research Council, 1996, International Standard Book Number 0-309-05377-3. The *Guide* is incorporated by reference in this section. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of the publication from the National Academy Press, 2101 Constitution Avenue, NW., Lockbox 285, Washington, DC 20055; or you may order it electronically via the Internet at <http://www.nap.edu>; or view it online at <http://oacu.od.nih.gov/regs/guide/guidex.htm>.

You may inspect a copy at NIH, NCCRR, 1 Democracy Plaza, 6701 Democracy

Boulevard, Bethesda, MD 20817–4874, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(1) The facility design and physical plant consist of the following components: Indoor design features; outdoor design features; construction and construction materials; physical barriers; shelter; service support space, including storage areas for food, supplies, and equipment; personnel and administrative support space; quarantine and isolation facilities; treatment area; heating, ventilation, and air conditioning (HVAC); food preparation area; and animal waste treatment.

(2) A housing system shall include indoor and outdoor enclosures that must be kept in good repair to prevent escape and injury to the chimpanzees, promote physical comfort, facilitate sanitation and servicing, and address the psychological well-being and social needs of the chimpanzees. Chimpanzees must be able to retreat from areas where they feel threatened or agitated by close human encounters or encounters with other chimpanzees.

(3) Indoor areas shall have special areas for social introductions and medical treatment. Quarantine and isolation facilities are required for the sanctuary. These facilities must be designed to prevent the spread of undesirable agents from quarantine and isolation rooms to other parts of the facility.

(4) Outdoor areas must provide sufficient ranging space and either natural or artificial structures that chimpanzees can use for shelter or nesting areas to sleep, rest, or seek refuge from rain, direct sun, wind, and extreme temperatures.

(5) Animal waste from the Sanctuary must be properly treated to remove known hazardous agents before discharging it into the environment in accordance with currently acceptable and effective waste treatment procedures, including current industry standards and Federal laws, regulations or guidelines, as applicable.

(6) An area for treatment of and performing veterinary clinical procedures on chimpanzees must be provided at each Sanctuary site. This area must be constructed and provisioned to perform emergency procedures, including minor surgery and emergency surgical procedures, complete physical examinations, and facilities for extended care of medical conditions as needed.

(b) *What security measures are required for the sanctuary?* The sanctuary must provide adequate security against unauthorized entry, sabotage, malicious damage, and theft of chimpanzees and property and must minimize any chance of escape by a chimpanzee. The security staff must have training and/or experience in methods and equipment designed to detect possible security breaches and the ability to respond to security events in a timely and effective manner. Perimeter containment shall be used to protect the compound housing the chimpanzees consistent with the recommendations of the *Guide* (incorporated by reference, see paragraph (a) of this section).

(c) *Is the sanctuary required to develop disaster and escaped animal contingency plans?* The sanctuary facility must prepare disaster and escaped animal contingency plans outlining simple and easy to follow plans for dealing with natural and man-made disasters and steps to be taken in case a chimpanzee escapes from the compound. The Sanctuary also must provide adequate security against unauthorized entry, sabotage, malicious damage, and theft of chimpanzees and property and must minimize any chance of escape by a chimpanzee. Primary barriers must be constructed to prevent escape of chimpanzees and secondary or perimeter barriers must prevent entry of unauthorized persons into the facility, consistent with the recommendations of the *Guide* (incorporated by reference, see paragraph (a) of this section).

§9.5 Chimpanzee ownership, fees, and studies.

(a) *Who owns the chimpanzees in the federally supported sanctuary?* The Federal Government retains ownership of chimpanzees owned by the Federal Government at the time they enter the sanctuary system. Non-federally owned

or supported chimpanzees will be owned by the sanctuary. The chimpanzees shall continue to be maintained in the sanctuary throughout their lifetime and shall not be discharged from the sanctuary except as specifically indicated in the CHIMP Act.

(b) *Is there a charge for placing chimpanzees in the sanctuary?* No fees shall be charged by the Sanctuary Contractor for federally owned or supported chimpanzees entering the sanctuary. Chimpanzees that were owned by a NPRC when the CHIMP Act became effective are also admitted without payment of fees. Fees for maintenance of the chimpanzees alluded to above are provided for in the contract between the Federal Government and the Sanctuary Contractor.

(c) *May the sanctuary agree to accept chimpanzees that are not owned by the Federal Government?* The sanctuary may accept chimpanzees that are not owned by the Federal Government subject to the following conditions:

(1) Ownership of the chimpanzee must be transferred to the sanctuary;

(2) Fees for these chimpanzees may be levied based on a range of considerations that include most importantly, the well-being of the chimpanzee and, secondarily, factors that include (but are not limited to) the resources available to support the chimpanzee; the health, age, and social history of the chimpanzee; and other relevant factors affecting the cost of caring for the chimpanzee. While chimpanzees not owned or supported by the Federal Government may be admitted to the sanctuary, federal funds may not be used for their support unless authorized by the Secretary or an authorized designee;

(3) Available space exists in the sanctuary; and

(4) An agreement exists between the sanctuary system and the NCR/NIH documenting that the chimpanzee may be brought into the sanctuary.

(d) *What additional conditions apply when nongovernmental owned chimpanzees transfer to the chimpanzee sanctuary?* The following additional conditions apply when nongovernmental owned chimpanzees transfer to the chimpanzee sanctuary:

(1) Chimpanzees transferred to the sanctuary sites must be permanently incapable of reproduction, for example, by vasectomy, tubal ligation, or another reliable procedure;

(2) Complete histories must accompany each chimpanzee. Any chimpanzee missing documentation for any period of research or other use may not be transferred to the Sanctuary without the concurrent authorization of the Sanctuary Contractor's Board of Directors and the NCR/NIH; the records may be created and retained in electronic form; and

(3) Appropriate screening of each chimpanzee must be performed to assess the likelihood of the chimpanzee being a health or safety threat to the care staff and/or other chimpanzees.

(e) *What are the criteria for acceptance and the fees for admission into the sanctuary for nongovernmental owned chimpanzees?* The chimpanzee Sanctuary Contractor, in conjunction with NCR/NIH, must establish criteria and a fee system for acceptance of nongovernmental owned chimpanzees. Funds collected for this purpose must be accounted for and used to help defray the expenses incurred in operating the sanctuary.

(f) *Under what circumstances might a chimpanzee from the sanctuary be returned to research at a United States research facility?* In December 2007, the CHIMP Act was amended by the "Chimp Haven is Home Act," which terminated the authority for the removal of chimpanzees from the sanctuary system for research purposes.

§9.6 Animal care, well-being, husbandry, veterinary care, and euthanasia.

(a) *What are the requirements for promoting the well-being of sanctuary chimpanzees?* The goal of chimpanzee housing and management in the sanctuary is to promote the chimpanzees' well-being.

(b) *What are the provisions for daily chimpanzee husbandry and care?* Adequate and proper care for chimpanzees in the sanctuary must be provided with respect to physical environment, housing and husbandry, behavioral management, and population management and

control. Specific requirements include the following:

(1) Chimpanzees must have access to food, water, and bedding at all times, unless medical or behavioral conditions dictate otherwise. Husbandry procedures shall represent current policies and practices and conform to standards set by a nationally recognized accrediting association in accordance with the *Guide* (incorporated by reference, see paragraph (a) of §9.4).

(2) Indoor primary enclosures must be cleaned as often as required to maintain a clean and healthy environment, with a minimum of once daily. Outdoor enclosures must be monitored daily and cleaned on a routine basis. Outdoor ranging areas will not require a routine cleaning schedule but must be monitored for excessive accumulation of waste or other unhealthy conditions. Housing areas shall provide sufficient space for chimpanzees to perform species-typical behavior and expression. Examples of such activities include but are not limited to natural movements, climbing, swinging, resting, running, group interactions, sleeping, etc. Feeding and watering implements must be sanitized at intervals required to maintain them in a sanitary condition, in accordance with the *Guide* (incorporated by reference, see paragraph (a) of §9.4).

(3) The federally supported chimpanzee sanctuary must employ a behavioral scientist knowledgeable in primate behavior and socialization requirements. This individual shall provide primary leadership in developing, implementing, and monitoring the chimpanzee behavioral guidelines for the sanctuary. Enrichment techniques used shall be currently accepted practices. The sanctuary must provide for the expertise to plan, administer, and evaluate the effectiveness of the well-being program.

(4) Many chimpanzees can be trained through positive reinforcement to cooperate with a variety of veterinary and chimpanzee care procedures. Efforts must be made to develop or maintain this capability for chimpanzees housed in the sanctuary to the extent possible. Trainers must use currently acceptable practices that do not include physical punishment.

(c) *What are the requirements for an adequate veterinary care and animal health program?* The sanctuary staff must provide sufficient resources of personnel, equipment, supplies, and facilities to enable the provision of adequate veterinary care as set forth in the *Guide* (incorporated by reference, see paragraph (b) of §9.4). For additional guidance see the American College of Laboratory Animal Medicine document, “The Provision of Adequate Veterinary Care,” available on the Internet at <http://www.aclam.org>.

(1) If the sanctuary houses chimpanzees with infectious diseases, it must have a veterinarian knowledgeable in the infectious diseases and care of chimpanzees. The Facility Veterinarian is responsible for establishing and implementing a health monitoring system specifically designed to meet the health requirements of chimpanzees in the sanctuary. Routine observation and the prevention of disease, metabolic conditions, abnormal behavior and injury must be a priority focus of the Facility Veterinarian and staff.

(2) Newly received chimpanzees must be quarantined for a period for physiological, psychological, and nutritional stabilization before their introduction to the rest of the group. The stabilization period must be lengthened appropriately if the chimpanzee has a significant medical problem or if abnormal medical findings are detected during the quarantine period. If the chimpanzee has not been given a complete physical examination within six months, an examination must be conducted during the stabilization period.

(3) The sanctuary must implement appropriate methods for disease surveillance and diagnosis of diseases, which may include the following:

(4) Tuberculin (TB) tests must be negative for two (2) consecutive tests before the chimpanzee is released from quarantine. Any chimpanzee that is suspected of harboring the TB organism, or that is diagnosed with TB will be isolated and treated until determined by the Facility Veterinarian to be of no health risk to other chimpanzees or humans. The Facility Veterinarian may recommend euthanasia in those cases that do not respond to

therapy and in which the chimpanzee consequently experiences undue pain and suffering that cannot be alleviated. The procedures noted under §9.6 (d) must be observed if euthanasia is necessary.

(5) Fecal samples must be checked for parasites and parasitic ova.

(6) A complete blood count and serum chemical panel must be obtained.

(7) Additional serum for banking and/or testing shall be obtained as appropriate by the Facility Veterinarian and is considered beneficial for chimpanzee health.

(8) If the donating facility did not test for the appropriate viruses, the sanctuary must perform a viral panel and serology for the various chronic hepatitis viruses and HIV.

(9) Additional tests or procedures that are deemed beneficial to the chimpanzees' health may be required by the Facility Veterinarian.

(10) Chimpanzees are susceptible to many of the vaccine preventable diseases of human childhood. Appropriate vaccines must be considered and administered if deemed necessary, at the discretion of the Facility Veterinarian, to protect the chimpanzees in the sanctuary. Methods of disease prevention, diagnosis, and therapy must comply with those currently accepted in veterinary medical practice. Arrangements with diagnostic laboratories must be established before chimpanzees arrive at the sanctuary.

(11) The sanctuary must minimize the use of physical and chemical restraint. Chimpanzees in the sanctuary shall be trained to permit certain procedures with minimal or no restraint. Such procedures may include injections, dosing or other treatments, and cage-side health observations. However, chemical sedation sometimes may be appropriate for certain necessary medical interventions or for the safety of the chimpanzee and caregivers. If physical restraint measures are necessary, due consideration must be given to the temporary or permanent effects upon the chimpanzee and human and animal safety concerns.

(12) Methods used to relieve pain must be documented in the chimpanzee medical or surgical records. These records will be available for review by

USDA and NIH representatives. The Facility Veterinarian must ensure that pain management is current and in accordance with acceptable veterinary medical practices.

(13) Chimpanzees must be cared for by qualified personnel on a daily basis, including weekends and holidays, to safeguard their well-being. Emergency veterinary care must also be available during these times. Notification procedures must be documented in the form of operating procedures.

(d) *Under what circumstances is euthanasia permitted?* As stated in section 481C(d)(2)(I) of the Public Health Service Act, as added by section 2 of the CHIMP Act, none of the chimpanzees may be subjected to euthanasia except when it is in the best interest of the chimpanzee involved as determined by the SCCC and the Facility Veterinarian. Therefore, euthanasia for medical or humane reasons is permitted. Euthanasia may be permitted for reasons of health or quality of life of the individual chimpanzee, including for disease, in connection with trauma, complications of aging, or for other humane reasons. The sanctuary must establish a policy on euthanasia that will provide conditions that must be met before euthanasia is permitted and guidance for performing euthanasia.

(1) Methods of euthanasia will be consistent with the most recent report of the American Veterinary Medical Association Panel on Euthanasia (2002), unless more reliable data becomes available. When euthanasia is performed, the veterinarian will determine the appropriate agent, and it will be administered only by properly trained personnel under the direction of the Facility Veterinarian. The decision to perform euthanasia will be made by the veterinarian in consultation with the Facility Director or Deputy Director.

(2) The SCCC will participate in the decision in nonmedical emergencies. All euthanasia decisions must be reviewed by the SCCC, preferably prior to euthanasia. In emergencies, where euthanasia has to be performed immediately by the Facility Veterinarian, the circumstances and the decision by the Facility Veterinarian will be presented at the next scheduled or special meeting of the SCCC. The NCRR

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Project Officer must be notified of the euthanasia event within 72 hours by electronic or telephonic means. Euthanasia of individual chimpanzees may negatively affect the care staff and appropriate counseling and psychological support shall be considered.

§ 9.7 Reproduction.

Chimpanzee reproduction is prohibited in the sanctuary. Therefore, all males must be sterilized by vasectomy before acceptance into the system, or, as a temporary measure, housed apart from females until they are sterilized. Vasectomies are advisable because they are minimally invasive and because effectiveness of the vasectomy may be validated through laboratory testing for semen. Seminal collection techniques must be carefully evaluated to avoid painful stimuli. Other proven methods of birth control may be used under special conditions deemed appropriate by the Facility Veterinarian and SCCC. The Facility Veterinarian must determine the appropriate test(s) to use to validate sterility. A veterinarian experienced in performing vasectomies in chimpanzees should perform the operation. Documentation must accompany each male accepted to the sanctuary system attesting to the fact that the male has been vasectomized and laboratory tests confirm that a segment of the Vas Deferens has been removed, or that the test used is reliable and is negative for sperm. The sanctuary must have a contingency plan for handling accidental births that includes the length of time the offspring is expected to remain with the mother.

§ 9.8 Animal records.

(a) *What records must be maintained for chimpanzees in the sanctuary and how are they managed?* (1) Contractors and Subcontractors operating the federal chimpanzee sanctuary system must maintain appropriate records to allow for accountability and disposition of chimpanzees under their care as required by the USDA Animal Welfare Regulations (9 CFR 2.35). The records may be created and retained in electronic form.

(2) The animal records currently required by the USDA Animal Welfare Regulations are also required for these

standards. Chimpanzees must be individually and permanently identifiable.

(3) Retrievable records must be maintained for a minimum of three years beyond the disposition or death of each chimpanzee in accordance with the Animal Welfare Regulations section 2.35(f) (9 CFR 2.35(f)). Original records or a copy must be transferred if the chimpanzee moves to a different facility. The records must include standard information, including permanent individual identification, research use(s), reproductive status (past and present), a summary or copy of the medical and behavioral history, the sire's identification number (if available), the dam's identification number, birth date, sex, and date acquired by the sanctuary. The disposition date must also be noted, if applicable, including whether the chimpanzee died or was transferred to another site in the federal sanctuary system. The records may be created and retained in electronic form.

(4) The contractor and any subcontractor(s) operating the federally supported chimpanzee sanctuary must provide special, quarterly, and annual progress reports to the designated Federal officials as identified in the contract. The annual report must also contain a statement that certifies the sanctuary is in full compliance with these standards of care regulation.

(b) *What are the rules governing the disposition of necropsy records?* The CHIMP Act requires that necropsy records from chimpanzees previously used in federally funded research projects be made available on a reasonable basis to investigators engaged in biomedical or behavioral research. In order to comply with this provision, the contractor for the sanctuary system must devise a plan that will allow interested parties to contact the sanctuary and receive necropsy records when they become available. Records may be provided free of charge but requesters may be required to pay for packaging and shipping costs. The records may be created and retained in electronic form.

§ 9.9 Facility staffing.

How many personnel are required to staff the chimpanzee sanctuary and what

qualifications and training must the staff possess? (a) The professional, managerial, and support staff must be sufficient to support the scope and diversity of the activities and chimpanzee population of the sanctuary. The level of staffing shall be adequate to ensure that the chimpanzees receive appropriate health care, are well cared for, and the administrative and fiscal operations are sound and in keeping with current practices required by NCCR/NIH;

(b) There must be a sufficient number of appropriately trained animal care and technical personnel to provide appropriate care to the chimpanzees at all times, including evenings, weekends, and holidays. The number of animal care staff to chimpanzee ratio shall be adjusted as experience is gained during the operation of the sanctuary. Sufficiently trained staff also must be available to maintain adequate behavioral enrichment;

(c) The Facility Director must be a person with experience in chimpanzee care and socialization techniques. In addition, the Director must have management and administrative experience;

(d) The Biosafety Officer must have experience in developing and monitoring biohazards and dealing with biosafety issues related to captive nonhuman primates. Experience in these areas dealing specifically with chimpanzees is desirable;

(e) The remaining staff, which may include part-time, full-time, or contractor Facility Veterinarian(s) and Behaviorist(s), must possess the skills, knowledge, and/or experience required to perform their duties, as elaborated within the regulation.

§ 9.10 Occupational Health and Safety Program (OHSP) and biosafety requirements.

(a) *How are employee Occupational Health and Safety Program risks and concerns addressed?* The sanctuary shall assure that an Occupational Health and Safety Program (OHSP) is developed and implemented in accordance with current veterinary medical practices and the guidelines and standards found in the *Guide* (incorporated by reference, see paragraph (a) of section 9.4);

(b) *How are biosafety concerns addressed?* The sanctuary shall institute and administer an effective biosafety program that addresses the biosafety hazards at that particular site. The program shall include identifying biohazards, outlining practices and procedures to be followed, providing personal safety equipment or protective clothing and equipment, and establishing a description of the facility requirements for working with hazardous agents or materials. Policies and procedures must be implemented to avoid exposure to environmental and animal hazards. Biosafety must be included in the training program for all Sanctuary employees. In establishing a program, the Sanctuary must use current accepted practices and publications prepared by the CDC, NIH, and professional societies specializing in biosafety. The input and guidance of personnel trained or experienced in biosafety are essential. Complete records of both clinical and experimental agent exposure must accompany each chimpanzee sent to the sanctuary. The donating facility must also provide recent testing (for example, serology, virus culture, histology) so that the sanctuary staff is fully aware of the health condition of the arriving chimpanzee. The records may be created and retained in electronic form.

§ 9.11 Animal transport.

The transportation of chimpanzees by surface or air must be in accordance with the requirements set forth in the Animal Welfare Act and Regulations and the International Air Transport Association (IATA) Live Animal Regulations and guidelines, as applicable.

§ 9.12 Compliance with the Standards of Care, and USDA and PHS policies and regulations.

(a) *How will compliance with the standards set forth in this part be monitored and what are the consequences of non-compliance with the standards?* The federally supported chimpanzee sanctuary must comply with the standards of care set forth in this part and include a statement in the Annual Progress Report certifying compliance with these standards of care in accordance with the terms of the current contract

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between NCRR and the Sanctuary Contractor. A designated representative of the Secretary will monitor compliance. The responsibility to monitor compliance with the standards is delegated to NCRR/NIH/HHS. The NIH/NCRR Project Officer for this contract will conduct scheduled site visits at least one time annually (or more often if necessary) and review monthly and quarterly reports submitted to the Project and Contract Officer. Subcontractors are subjected to the same provisions. Failure to comply with the standards set forth in this part, or to correct deficiencies noted within the allowable time period, could result in termination of the contract by the Federal Government (HHS/NIH), or allow the Secretary to correct the deficiencies according to the terms and conditions outlined in the contract. The Secretary may impose additional sanctions on the contractor up to, and including, authorizing assumption or reassignment of the management of the sanctuary contract.

(b) *To what type of outside review or inspection will the federally supported sanctuary be subjected?* As noted in paragraph (a) of this section, the contractor for the sanctuary will be monitored on a regularly scheduled basis by representatives of NCRR/NIH/HHS. The NCRR representative will use facility site visits, reports, personal contact, and any other means as appropriate to ensure compliance with these standards. The contractor and subcontractors are required to obtain and maintain an Animal Welfare Assurance from NIH's Office of Laboratory Animal Welfare (OLAW) when chimpanzees are used for noninvasive studies as authorized in the CHIMP Act. In addition, the sanctuary must achieve accreditation by a nationally recognized animal program accrediting body (such as the AAALAC, the AZA, or similar recognized body) within a time frame to be determined by NCRR/NIH. The federally supported sanctuary must comply with the requirements set forth in the Animal Welfare Regulations (9 CFR parts 1 through 3).

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§ 9.13 Other federal laws, regulations, and statutes that apply to the sanctuary.

(a) Animal Welfare Act (7 U.S.C. 2131–2159).

(b) Animal Welfare Regulations, 9 CFR, subchapter A, parts 1 and 2; part 3, subpart D—Specifications for the Humane Handling, Care, Treatment, and Transport of Nonhuman Primates.

PART 10—340B DRUG PRICING PROGRAM

Sec.

Subpart A—General Provisions

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10.20 Drugs eligible for purchase Under 340B.

10.21 Exclusion of orphan drugs for certain covered entities.

AUTHORITY: Sec. 340B of the Public Health Service Act (42 U.S.C. 256b), as amended; Sec. 215 of the Public Health Service Act (42 U.S.C. 216), as amended; Sec. 526 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 360bb); Sec. 701(a) of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 371(a)); Sec. 1927 of the Social Security Act, as amended (42 U.S.C. 1396r–8).

SOURCE: 78 FR 44027, July 23, 2013, unless otherwise noted.

Subpart A—General Provisions

§ 10.1 Purpose.

This part implements section 340B of the Public Health Service Act (PHSA) “Limitation on Prices of Drugs Purchased by Covered Entities.”

§ 10.2 Summary of 340B Drug Pricing Program.

Section 340B of the PHSA instructs the Secretary of Health and Human Services to enter into agreements with